



May 17, 2004

Office of Nutritional Products,  
Labeling and Dietary Supplements (HFS-810),  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy.  
College Park, MD 20740

MAY 24 2004

**Section 403(r)(6) Notification**

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

**Support for Hot Flashes/Night Sweats  
Menstrual Cycle Support**

**May offset a decline in estrogen and help balance hormone levels during your reproductive years and beyond. It may also help normalize menstrual cycles of women in childbearing years. Clinical studies have shown that black cohosh can help relieve menopausal symptoms such as hot flashes and night sweats. Lecithin may help optimize the benefits of black cohosh by contributing to healthy cell membrane structure and function.**

on the following product:

**YourLife® Black Cohosh**

Very truly yours,

**Leiner Health Products**

A handwritten signature in dark ink, appearing to read 'W Cochran', written over a horizontal line.

William Cochran, Manager of Regulatory Affairs

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Office of Nutritional Products,  
 Labeling and Dietary Supplements (HFS-810),  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 (continued)

The following brands also use the above statement:

*Albertson's*  
*BI-MART*  
 BIO BALANCE®  
 COUNCIL LABS®  
 CVS®  
 ECKERD®  
*equate®*  
 Hannaford®  
 HealthLine  
 health PRIDE  
*Kash n' Karry*  
*KIRKLAND Signature™*  
 Kroger®  
 Longs  
 MARC'S  
 Member's Mark  
 MEIJER™

Nature's Origin®  
 NATURE'S VALLEY™  
 NATURITE®  
*NUTRA CHOICE*  
 NUTRI-BLEND  
 Osco®  
 PHARMACIST FORMULA®  
 BODYCOLOGY™  
 SAFEWAY SELECT™  
 Sav•on™  
*Shaw's*  
*ShopKo®*  
 Spring Valley®  
 TARGET®  
 TOP CARE®  
 TRUNATURE®  
 Wegmans®